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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,047	12/07/1998	KYOGO ITOH	20-4491P	2396

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 06/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,047

Applicant(s)

ITOH ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 10, 11, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 24.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Request for Continued Examination

1. The request filed on 4/22/02 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/202047 is acceptable and a RCE has been established. Claims 6-9 and 12-13 are currently under prosecution. An action on the RCE follows.
2. Claims 1-15 are pending.
Claims 6-8 have been amended in paper #18 and 22.
3. Claims 1-5, 10-11, 14-15 have been withdrawn.
4. Claims 6-9 and 12-13 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejections.

Rejections Withdrawn

11. The rejection of claims 6, 8, and 13 under 35 U.S.C. 102(b) as being anticipated by Nakao et al (Cancer Res. 55:4248-4252, 10/1/95, IDS #2) is withdrawn in view of the amendment to the claims (for claim 6) and reconsideration (for claims 8 and 13).
13. The rejection of claims 6-9 and 12-13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Response to Arguments

11. The rejection of claims 7 and 12 under 35 U.S.C. 102(b) as being anticipated by Nakao et al (Cancer Res. 55:4248-4252, 10/1/95, IDS #2) is maintained and made again.

The response filed 4/22/02 and 2/22/02 has been carefully considered but is deemed not to be persuasive. The response of 4/22/02 did not address this rejection. The response filed 2/22/02 states that claim 7 has been amended to recite "purified" and this clearly distinguishes claim 7 over Nakao et al (see page 10 of response of 2/22/02) and "it is impossible for a skilled person to obtain the peptide fragment of claim 7 in accordance with the teaching of Nakao et al. as explained above in Dr. Itoh's second Declaration, especially on pages 3 and 4" (see page 11 of response of 2/22/02) and "Further, KE-4 cell is a tumor cell established from an isolated cell originated from a particular tumor patient, and hence had not been publicly available before its deposition date (May 23, 1997)" (see page 11 of response of 2/22/02). In response to these arguments, the limitation of "purified" does not mean only one or to homogeneity. Nakao et al separated the peptides by HPLC and this would be a "purified" step. With regard to the Declaration of Dr. Itoh, it has been carefully considered but is deemed not to be persuasive. The Declaration states that fraction 23 was obtained through HPLC of a sample consisting of peptides having molecular weight of 3000 or about 30 amino acids and hence could not contain the tumor antigen protein of the present invention consisting of 800 amino acids. In response to this argument, claim 7 is directed to peptide fragments and peptides of 30 amino acids meet this limitation. As stated in the

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Advisory Action mailed 3/7/02 the art of Nakao et al does not read on the full length protein of 800 amino acids. Also there is nothing in the declaration that states that the KE-4 cells were not publicly available.

The following is a NEW GROUND of rejection

Claim Rejections - 35 USC § 112

12. The rejection of claims 6-9 and 12-13 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 has been amended to recite the limitation of "a protein of about 800 amino acids which is encoded by a DNA which hybridizes to SEQ ID NO:1 under stringent conditions....wherein said protein yields, through intracellular decomposition, peptide fragment(s)....". The amendment filed 4/22/02 has been carefully considered but is deemed not to be persuasive. The response seems to argue that a sequence which hybridizes to SEQ ID NO:1 or the complement of SEQ ID NO:1 is supported by the specification and a substitute sequence listing was provided with the anti-sense strand (see pages 4-6 of response). In response to these arguments, the specification supports DNA which hybridizes to SEQ ID NO:1 (or inherently its complement) or a

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variant DNA which hybridizes to SEQ ID NO:1 (see page 9, lines 5-10). The specification does not support just any protein of about 800 amino acids which is encoded by a DNA which hybridizes to SEQ ID NO:1. The specification does teach SEQ ID NO:2 which is encoded by SEQ ID NO:1 and SEQ ID NO:2 is 800 amino acids in length. There is no support for just any protein of about 800 amino acids that would be encoded by a DNA which hybridizes to SEQ ID NO:1. Applicant is required to provide support for the limitation in the specification as originally filed or remove it from the claims.

Claims 6-9 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 has been amended to recite the limitation of "a protein of about 800 amino acids which is encoded by a DNA which hybridizes to SEQ ID NO:1 under stringent conditions....wherein said protein yields, through intracellular decomposition, peptide fragment(s)....". The specification teaches a protein of 800 amino acids of SEQ ID NO:2 which is encoded by SEQ ID NO:1. The specification does not disclose any other protein that is about 800 amino acids that has the required function recited in claim 6 (c). Although the claim does have some functional language of wherein the peptide fragments bind to MHC class I antigen and is recognized by CTLs this limitation is not limiting because any tumor antigen peptide that is broken down would have this

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function as it would be immunogenic and be recognized by CTLs. The claims read on a broad genus of proteins that include not only SEQ ID NO:2, but any protein of about 800 amino acids. The specification demonstrates reduction to practice of only a single species, SEQ ID NO:2. The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed. Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

Summary

14. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER